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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/711,295 | 11/14/2000 | Vicky L. Funanage | 2019659-0139 | 6833 |

7590 03/24/2003

McGuire Woods
One James Center
901 East Cary Street
Richmond, VA 23219-4030

| EXAMINER |
|---|
| O HARA, EILEEN B |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/711,295 | FUNANAGE ET AL. | |
| | Examin r | Art Unit | |
| | Eileen O'Hara | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --*

**Period for R ply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *2 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6,8-11 and 13-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-11 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

1. Claims 1-6, 8-11 and 13-16 are pending in the instant application. Claims 7 and 12 have been canceled as requested by Applicant in Paper Number 9, filed Jan. 2, 2003.

### *Withdrawn Rejections*

2. The rejection of claims under 112 § 1 is withdrawn in view of Applicants' amendment.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 6, 8-11 and 13-16 remain rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention, for reasons of record in the previous Office Action, Paper No.7, at page 3, and for the reasons below.

Applicants traverse the rejection and assert that the level of leptin in premature breast milk is significantly lower than leptin levels in established breast milk, and cite Resto et al. (2001) as reporting that leptin levels in premature breast milk as 5.28+/-24.79 compared to the levels reported in established breast milk, 73.22+/-39.08. Applicants also cite Cinaz et al., 1999, which teaches that small-for gestational age infants show only a marginal increase (23%) in serum leptin levels after breast feeding whereas appropriate-for-gestational age and large-for-gestational age infants demonstrate much larger increases of 47% and 136% respectively, indicating that premature mother's breast milk does not have leptin levels sufficient to enhance

surfactant production, and also Spear et al. (2001) which teases that leptin levels are low in premature infants and remain low during the duration of the premature infant's hospitalization despite adequate nutrition, including breast feeding.

Applicants' arguments have been fully considered but are not deemed persuasive. The references of Resto et al., Cinaz et al. and Spear et al. were not included in the response and the evidence could therefore not be considered. Additionally, the levels of leptin present within premature milk are still within the ranges of claims 6 and 11. For example, there are approximately 2.2 lbs/kilogram, and a premature baby of 4.4 lbs would weigh about 2 kg. Therefore, the minimum leptin to be administered (0.1ng/kg) would be 0.2 ng. If the leptin levels in premature breast milk is about 5.28 ng/ml, then per ml of milk, there would be 26 times (5.28/0.2) the required level of leptin necessary, so that premature breast milk would have more than enough leptin. Therefore, the rejection is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-6, 8-11 and 13-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Torsday it al., FASEB Journal, March 15, 2000, Vol. 14, No. 4, and/or Torsday et al., Pediatric Research, 378A, March 2000, and further in view of Griese, Eurpoean Respiratory Journal, 1999, and Halliday et al., In: Hot Topins in Neonatology, 1999, and O'Donnell et al.,

Am. J. Resp. Crit. Care Med. 159, 1999, for reasons of record in the previous Office Action, Paper No. 7 at pages 4-6, and for the reasons below.

Applicants traverse the rejection and assert that Griese and Halliday et al. do not show, teach or suggest that administering leptin to an individual will enhance surfactant production in an individual, that O'Donnell does not disclose, teach or suggest that leptin may be administered to an individual to enhance surfactant production, and this deficiency is not cured by the Torsday et al. references. Applicants assert that Torsday et al. show that leptin increases phosphatidylcholine levels in an established cell line, and do not show that leptin increases the levels of surfactant proteins A, B and C, and do not demonstrate that leptin increases phosphatidylcholine levels in an animal model nor in lung cells or tissue with insufficient production of surfactant as would be found in premature infants with RDS or in adults with ARDS. Applicants cite Mendelson and Boggaram, 1991, Rooney, Young, and Mendelson, 1994 and Whitsett et al., 1995, as demonstrating that the genes encoding the surfactant proteins are regulated independently from each other and from the genes responsible for regulating phospholipid synthesis. Applicants further assert that surfactant preparations that have the surfactant proteins are more efficacious in the prevention and treatment of RDS in prematurely born infants than are the synthetic phospholipids mixtures, and that none of the references, alone or in combination, discloses, teaches or suggests that leptin may be administered to an individual to enhance lung surfactant production.

Applicants' arguments have been fully considered may be deemed persuasive, but because the references of Mendelson and Boggaram, Rooney, Young, and Mendelson, and

Whitsett et al. were not included in the response, that evidence could therefore not be considered. Upon submission of these references the rejection will be reconsidered.

It is believed that all pertinent arguments have been answered.

***Conclusion***

5. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600